EXHIBIT 516

Expert Report of Robert L. Buskey

Nationwide Prescription Opiate Litigation
MDL No. 2804

May 31, 2019

HIGHLY CONFIDENTIAL

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I. INTRODUCTION

1. I was engaged by counsel at Reed Smith LLP, on behalf of AmerisourceBergen Drug Corporation ("AmerisourceBergen" or "ABDC"), to serve as an expert witness in *In re National Prescription Opiate Litigation*, MDL 2804 (N.D. Ohio) for the Summit and Cuyahoga County consolidated cases.[1]

2. A full list of materials reviewed and considered in preparation of this report and/or cited in this report is attached as Appendix A. To the extent I refer to information within the body of this report and that information is not set forth in Appendix A, the omission is an oversight. This report and Appendix A should be read collectively as they are intended to set forth my opinions regarding validity and material I relied on in forming these opinions.

3. My opinions set forth in this report are stated to a reasonable degree of professional certainty. I reserve the right to supplement or amend this report upon review of additional materials or information provided to me by the parties in this case, and/or at the request of counsel for additional analyses. I further reserve the right to offer opinions within my area of expertise in response to additional opinions and/or subjects offered or addressed by other experts on behalf of Plaintiffs or other Defendants.

4. I reserve the right to use demonstratives, graphs, charts, and other visual aids to demonstrate various aspects of my testimony.

II. PROFESSIONAL BACKGROUND AND QUALIFICATIONS

5. My name is Robert L. Buskey. I am Co-Founder and Managing Director of BBG Consulting LLC ("BBG"). My CV is attached as Appendix B.

6. I received my B.A. in Economics and Psychology at State University of New York at Stony Brook in 1980.

7. From 1986-2011, I was employed by the United States Drug Enforcement Administration ("DEA"). During my time at DEA, I held a top secret security clearance with access to the Sensitive Compartmentalized Information Program.

8. From 1986-1991, I was a special agent/criminal investigator, conducting criminal and civil investigations of criminal organizations.

9. From 1991-1995, I managed the New York Field Division Recruitment program. From 1995-1996, I was the non-drug evidence supervisor. From 1996-1997, I again served as recruitment coordinator.

[1] It is my understanding that my report is being served on the DOJ to allow DOJ the opportunity to request that certain portions of my report be redacted.

10. From 1998-2005, I was a member of the DEA Trauma Team, responsible for informing family members of crises of family members serving in DEA, including death notifications and other family crises.

11. From 1997-2001, I was a Supervisory Special Agent for the Mobile Enforcement Team and Westchester Task Force, where I supervised and conducted criminal and civil investigations into drug trafficking.

12. I became the Resident Agent in Charge for Westchester, New York from 2000-2001.

13. From 2001-2002, I served at DEA Headquarters as Staff Coordinator in the Office of Operations Management, Investigative Support Section, managing state and local task force deputization program, other cross-designation law enforcement programs, undercover documents, prisoner transfer and repatriation programs, and represented the agency for several classified programs.

14. From 2002-2004, I again served at DEA Headquarters as an Inspector for the Office of Inspector General, Office of Inspections, conducting on-site inspections of headquarters and field offices to determine mission effectiveness, audit financial operations, and make findings and recommendations for improvement and compliance with DEA rules, regulations, and policies. I also served on the Shooting Incident Investigative Response Team and the Crisis Management Team. In this role, I also worked on creating a paperless environment and reviewed desk audit requests for promotions to GS-13.

15. From 2004-2005, I served as Acting Assistant Special Agent in Charge for Division 40, New York Field Division, supervising five Group Supervisors and overseeing 50 federal, state, and local law enforcement officers in missions to disrupt and dismantle drug trafficking organizations.

16. From 2004-2009, I served as Supervisory Special Agent for the Tactical Diversion Squad in the New York Field Division. I managed this new, hybrid investigative unit, with a goal to dismantle and disrupt drug trafficking organizations facilitating, diverting, and distributing scheduled pharmaceuticals, controlled substances, and List I chemicals. I supervised and formulated strategies to combat DEA registrants and criminal syndicates violating the Controlled Substances Act ("CSA"). I tracked assets gained through laundering money and the transport of bulk currencies domestically and internationally. From 2010-2011, I was the Assistant Special Agent in Charge, Division 30, New York Field Division, supervising four Group Supervisors and 60+ federal, state, and local law enforcement officers to disrupt and dismantle drug trafficking and money laundering organizations, including at all New York area airports. I retired from the DEA in 2011.

17. I co-founded BBG in 2013. BBG is a risk management firm operating in the areas of compliance, investigations, due diligence, business and integrity, and safety and security, including pharmaceutical compliance. At BBG, I conduct on-site reviews and revise standard operating procedures for major pharmaceutical companies, including manufacturers. I conduct onsite reviews on behalf of pharmaceutical distributors to augment their evaluation of

their compliance programs, including order monitoring programs' compliance with the CSA and implementing regulations. I analyze dispensing reports and identify possible red flags in those reports. I review and evaluate distributors' record-keeping, controlled substances handling, security apparatus, and due diligence policies.

18. I became licensed as a private investigator in the state of New York in 2015. My license is up-to-date.

19. In the course of my employment, I have evaluated distributor compliance with the CSA.

20. Throughout my time at the DEA and my consulting work, I've learned that compliance is an ever-evolving environment. The fact that a company changes its compliance processes, procedures, or programs does not indicate or mean that prior processes, procedures, or programs were flawed.

III. DISCLOSURES AND METHODOLOGIES

21. I am being compensated at the rate of $250 per hour for review of documents and information, preparation of this report, and deposition testimony. I am being compensated at the rate of $350 per hour for my time spent testifying in court in this case. My compensation is not based on the outcome of this litigation.

22. I have not previously provided expert testimony at a deposition or a trial.

23. Throughout this report, I use the phrase "Diversion Control Program" to address ABDC's entire system of compliance with the CSA and DEA's informal guidance provided to distributors over time, to include new and ongoing customer due diligence, and the identification and review of orders of interest to determine if they are suspicious.

IV. SUMMARY OF OPINIONS

24. My opinions are based on my background, training, education, and experience; my review and knowledge of the applicable law and regulations; and my review of the information produced in this litigation, among other things. All of my opinions are stated to a reasonable degree of professional certainty.

25. Below is a summary of my opinions. That summary is intended for ease of reference, and is not intended to reflect the entire body of my opinions. This summary of opinions is also supported and informed by the information contained in the body of the report that follows. There are other opinions, not summarized below, which are contained within this report. All opinions I provide are stated to a reasonable degree of professional certainty and are all based on my background, training, education, experience, and my review of the information produced in this litigation, among other things.

26. **Opinion 1:** The Controlled Substances Act, and the implementing regulations relating to suspicious order monitoring systems, are subjective and the DEA has afforded registrants wide discretion to design and operate systems to meet their regulatory requirements.

27. **Opinion 2:** ABDC has at all times maintained sufficient and effective controls to guard against the diversion of controlled substances into other than legitimate medical, scientific, or industrial channels.

28. **Opinion 3:** Over the relevant time period, the DEA had actual hands-on involvement with the design and implementation of ABDC's diversion control program. In 1998, the DEA helped develop and explicitly approved the nationwide implementation of Bergen Brunswig's new system for identifying and reporting suspicious orders – a program that remained in effect until 2007. In 2007, the DEA worked alongside ABDC in developing an enhanced diversion control program. Up to the present, ABDC has continued to solicit input from DEA on its diversion control program.

29. **Opinion 4:** There is no requirement set forth in the Controlled Substances Act or the implementing regulations that a registrant should not ship an order that it has reported to the DEA as suspicious. The Bergen Brunswig suspicious order monitoring system that the DEA helped develop and explicitly approved for nationwide use reported suspicious orders after they had already shipped. ABDC and its processor companies' pre-2007 practice of reporting suspicious orders to the DEA after the order had been shipped was consistent with and pursuant to the approved program and general industry practice in that pre-2007 time period.

V. REGULATION OF CONTROLLED SUBSTANCES

30. The laws regarding distribution of controlled substances have not been changed since 1971. Similarly, the regulations in the Code of Federal Regulations ("CFR") offering formal, legal guidance to distributors of controlled substances do not reflect the modern distribution business.

31. Despite being aware that the pharmaceutical industry viewed the regulations as confusing and providing little to no guidance on what a "suspicious order" is, the DEA has not changed its regulations since 1971.[2]

32. Recognizing that there is a need to update the regulations, the DEA has been working on a revised version of the regulation relating to the definition of "suspicious order" for at least four years but has failed to publish anything.[3]

33. DEA has not made this new regulation a priority because there is no "urgency of the public interest" according to them.[4]

34. While DEA has offered informal guidance to distributors at times in the past 20 years, such guidance has been informal, inconsistent, and does not appear in the Controlled Substances Act or in the implementing regulations in the CFR.

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[2] Dep. of Demetra Ashley, March 15, 2019, at 70:7-11 ("Q. Has the DEA, in your personal knowledge, provided any additional written definition of what a suspicious order is? THE WITNESS: Published publicly, no.") (objection omitted).
[3] *Id.* at 95:15-24; 118:8-19; 122:18-123:2.
[4] *Id.* at 121:20-122:11.

35. There are two "sides" to DEA: diversion and enforcement. The enforcement side is funded via taxpayer money. The enforcement side historically focused on drug cartels, trafficking of illegal drugs, and violent crime associated with drugs.

36. The diversion side is funded with registration fees paid by registrants in the pharmaceutical industry. The diversion side historically focused on registrants in the closed supply chain, and primarily conducted audits and investigations regarding diverted pharmaceutical medications.

37. In the early 2000s, DEA began a shift toward incorporating enforcement tactics and strategies into the diversion side of DEA. That shift affected DEA's positions, guidance, and willingness to work with registrants, including distributors. The approach became less collaborative.

38. The shift was spurred on by the growth in internet pharmacies and distribution of hydrocodone products.

39. One example of that shift is the creation of the Tactical Diversion Squads ("TDS") in the early 2000s, where special agents from the traditional enforcement side of DEA were placed into the diversion side of DEA to conduct investigations relating to the closed supply chain and pharmaceutical manufacturing, distribution, dispensing, and prescribing. My New York TDS was one of the first TDS created.

40. I was recruited to join a TDS because I had a computer and internet background, and in the early 2000s, internet pharmacies were a priority of the DEA. Many on my team were computer and internet savvy, including drug related activity in chat rooms and other internet-hosted spaces.

41. TDS were cross-functional teams involving personnel such as agents, criminal investigators, diversion investigators, state and local police investigators, financial analysts, and administrative personnel and support.

42. The TDS I managed investigated physicians, pharmacies, and an employee of a manufacturer who had stolen prescription medication. I do not recall investigating any distributors.

43. DEA's insertion of enforcement agents into the diversion side marked a sea change in the way in which diversion operated. This change brought the enforcement mission directly into the diversion side.

44. TDS reports to the Assistant Special Agent in Charge (enforcement side) and also makes reports to the Diversion Program Manager (diversion side). The Assistant Special Agent in Charge determines priority and reports through the Associate Special Agent in Charge to the Special Agent in Charge of the DEA Field Division; diversion is kept informed but does not determine TDS priority.

45. In my experience, DEA does not investigate every suspicious order report. DEA affords significant discretion to each field office regarding how and whether to investigate

suspicious orders. That discretion depends upon each office's resources and workload, as well as the priority, and importance of suspicious order reports generally and a particular suspicious order report.

46. TDS sometimes received investigative leads through ARCOS. I cannot recall an instance where a suspicious order report worked its way into TDS and served as the reason for an investigative lead.

47. In my experience with the DEA, investigative techniques were not always used in a uniform way; investigators knew what tools they had available to them and would pick and choose, according to their discretion, which tools to use for a particular investigation.

48. DEA was empowered to and could have changed suspicious order and registrant-related regulations had it chosen to, just like DEA did with Methamphetamine Control Act and Ryan Haight Act.

49. I have reviewed the report of James Holifield (May 31, 2019) ("Holifield Report"). I agree with Sections V through VII of the Holifield Report and would opine similarly at trial if asked. I include several additional points regarding DEA trends and the regulatory environment in the above section.

VI. ABDC MAINTAINED SUFFICIENT, REASONABLE, AND EFFECTIVE CONTROLS TO GUARD AGAINST DIVERSION OF CONTROLLED SUBSTANCES.

50. ABDC is a licensed wholesale distributor of pharmaceutical products, including over-the-counter pharmacy products, prescription medications, and controlled substances. It manages the transportation of medications, including controlled substances, from manufacturers to pharmacies and hospitals.

51. AmerisourceBergen was formed in 2001 when AmeriSource Health Corporation ("AmeriSource Health") and Bergen Brunswig Corporation ("Bergen Brunswig") merged. [5]

52. Prior to the merger in 2001, Bergen Brunswig and AmeriSource Health operated separately.

53. ABDC designed, implemented, maintained, and enhanced its Diversion Control Programs over the relevant time period.

54. For purposes of this report and consistent with my review of the documents and testimony provided by ABDC witnesses, I've been asked to provide opinions on ABDC's diversion control programs for the periods from: (1) pre-1998; (2) 1998-2007; (3) 2007-2015; and (4) 2015 through the end of the discovery period.

[5] AmerisourceBergen, *Our History*, https://www.amerisourcebergen.com/abcnew/about-our-history (last visited May 28, 2019).

55. Distributors were afforded significant discretion in designing, implementing, and improving or making changes to their programs to comply with DEA's statutory and regulatory suspicious order monitoring requirements.[6]

56. Investigation into whether an order is suspicious is a subjective, not objective, process. Resolution of whether that order is suspicious will depend on the order and customer information available to the registrant evaluating that order.

57. DEA has not issued regulations on due diligence or "know your customer" requirements. Moreover, DEA has not issued any best practices regarding how registrants know their customers.

58. The fact that an order might meet the statutory definition of suspicious does not mean that the order, if shipped, would in fact be diverted. Conversely, an order that does not meet the definition of suspicious could be diverted after it is shipped – for example, if a prescription is shared with or stolen by a patient's friend or family member.

59. Based on my background, training, education, experience, and my review of the information produced in this litigation, among other things, it is my opinion that ABDC and its predecessor companies have always maintained effective controls against diversion and have always had effective systems in place to detect and report suspicious orders pursuant to 21 CFR § 1301.74.[7] The diversion control program was reasonable as designed and executed by ABDC and its predecessor companies.

A. Bergen Brunswig's Pre-1998 Diversion Control Program Included Confirmation That Customers Were Licensed, Maintained The Security Of Controlled Substances, And Employed Different Methods of Identifying and Reporting Suspicious Orders.

60. Prior to 1998, Bergen Brunswig developed and operated a diversion control program that: (1) ensured that its customer base was licensed and registered with the DEA and appropriate State Boards of Pharmacy; (2) maintained the safety, security, and integrity of the medications passing through its distribution centers; and (3) detected and reported suspicious orders to the DEA.[8]

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[6] *See*, *e.g.*, Dep. of Thomas Prevoznik, April 17, 2019, at 178:19-179:3 (admitting that there was no industrywide guidance provided in 2008 or forward as to how to design or implement suspicious order monitoring programs); 179:22-180:15 (DEA agrees that there is more than one way to design and operate a system that can identify and report suspicious orders; there is no single feature that makes a suspicious order monitoring system compliant; and DEA leaves it up to the registrant to design a system that works with its own business model and customer base).

[7] A suspicious order is defined as "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 CFR § 1301.74(b).

[8] *See* ABDCMDL00315783 at 91. It is my understanding that AmeriSource Health had a similar diversion control program. For purposes of suspicious order monitoring, AmeriSource Health also had postings in the controlled substances cages and vaults. Dep. of Stephen Mays, October 24, 2018, at 81:19-82:7. The postings listed quantities for controlled substances that were permissible. *Id.* Order fillers could compare the quantity ordered in a particular order to the quantities on the posting and determine whether the quantity exceeded the posted amount for that controlled substance. *Id.* If so, the filler could flag the order to a supervisor. *Id.*

61. Bergen Brunswig maintained the safety and security of the medications passing through its distribution centers. It had cages and vaults for additional security of controlled substances.

62. During this time period, Bergen Brunswig developed a model excessive purchase report that was used by many other distributors to comply with their suspicious order reporting requirements.[9] The excessive purchase report listed total customer purchases for the reported month which exceed pre-determined multiples of the average monthly purchases of Bergen Brunswig's total customer base.[10] This report was submitted monthly via certified mail.[11] The pre-determined multiplier was three for ARCOS-reportable items (Schedule II and reportable Schedule III controlled substances) and six for non-ARCOS controlled substances.[12] In most instances, distribution centers sent in these reports to the local DEA field office with oversight over each distribution center,[13] and as such the DEA knew that Bergen Brunswig was using a multiplier of three for ARCOS-reportable items.

63. In addition to submitting monthly excessive purchase reports, Bergen Brunswig reported suspicious orders telephonically by calling various DEA field offices. In an average year, Bergen Brunswig made approximately 12,000 calls to DEA field offices across the country to report suspicious orders orally.[14]

64. Bergen Brunswig received inconsistent guidance from DEA field offices on the telephonic reporting of suspicious orders.[15] Some DEA field offices asked Bergen Brunswig to either limit the number of phone calls or report suspicious orders in other ways.[16]

65. In 1996, in response to feedback it received from the various DEA field offices relating to its telephonic reporting of suspicious orders, Bergen Brunswig approached DEA about developing a new program to detect and report suspicious orders electronically to the DEA.[17]

66. Based on my background, training, education, experience, and my review of the information produced in this litigation, among other things, it is my opinion that Bergen Brunswig's pre-1998 diversion control program maintained effective controls against diversion and was an effective system to detect and report suspicious orders pursuant to 21 CFR § 1301.74. The pre-1998 diversion control program was reasonable as designed and executed.

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[9] *See* ABDCMDL00315783 at 91.
[10] *See id.*
[11] *See id.*
[12] Dep. of Chris Zimmerman, August 3, 2018, at 124:23-125:5.
[13] ABDCMDL00315783 at 91.
[14] *Id.*
[15] *See id.*
[16] *Id.* at 92.
[17] *Id.*

B. In 1998, DEA Approved Bergen Brunswig's New System For Identifying And Reporting Suspicious Orders Nationwide.

1. Bergen Brunswig Developed a New Suspicious Order Reporting System With Assistance From The DEA.

67. Between 1996 and 1998, Bergen Brunswig developed, tested, and implemented a new computer-based suspicious order monitoring system with the DEA which was ultimately approved by the Chief of the Liaison and Policy Section of the Office of Diversion Control at the DEA for nationwide implementation on July 23, 1998.[18]

68. Before implementing this program, in 1996, Chris Zimmerman, the Manager of Corporate Security at Bergen Brunswig, wrote to Thomas Gitchel, the Chief of the Liaison and Policy Section at the DEA, in an effort to work with the DEA to develop this new suspicious order monitoring system.[19] Mr. Gitchel was the highest ranking official at the DEA responsible for interpreting the suspicious order monitoring regulations.

69. Bergen Brunswig developed a computer program that would compare a customer's controlled substance orders against a standard representing an average of the customer's prior four months of orders.[20] All orders that exceeded a specified percentage of the customer's prior four month average order history would be faxed to the DEA field office daily.[21] This report would be in addition to monthly excessive purchase reports.[22]

70. The report sent to DEA field offices would include the following information: (1) customer's name, address, and DEA number; (2) item description, NDC number, and order date; (3) active ingredient volume order; (4) the average of the customers' prior four month orders (*i.e.* the customer's "allowance"); and (5) the active ingredient shipped.[23]

71. Bergen Brunswig highlighted that "[o]ne key question would be the assignment of the percentage value that a customer's order would have to exceed before that order would appear on the report," as the value chosen "would directly impact the size of the report."[24] Bergen intended to obtain DEA input to "identify the optimum percentage value that will yield DEA the highest quality information without sacrificing administrative cost and efficiency."[25]

72. Mr. Zimmerman's letter to the DEA sparked a collaborative effort between Bergen Brunswig and the DEA to develop and test this new system.[26]

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[18] *See* ABDCMDL00315783; US-DEA-00025671.
[19] *Id.* at 91-93.
[20] ABDCMDL00315783 at 92.
[21] *Id.*
[22] *Id.*
[23] *Id.*
[24] ABDCMDL00315783 at 93.
[25] *Id.*
[26] *See generally* ABDCMDL00315783; US-DEA-00025671.

73. The DEA weighed in on the contents of the proposed report, and suggested that the quantity of drugs ordered be "expressed in dosage units rather than weight of the active ingredient."[27]

74. The DEA then agreed to test Bergen Brunswig's new program for three of Bergen Brunswig's distribution centers.[28] With DEA's approval, Bergen Brunswig's three distribution centers—located in Valencia, California, Corona, California, and Honolulu, Hawaii—began submitting the daily faxes to DEA's Los Angeles field office.[29]

75. DEA field offices responded positively to this new program.[30]

2. The Program Bergen Brunswig Developed With The DEA Included Reporting Orders That Had Been Shipped.

76. The DEA was fully aware that the program being developed by Bergen Brunswig was intended to meet the suspicious order reporting requirement of 21 CFR 1301.74. Mr. Zimmerman specifically stated in his correspondence to the DEA that the purpose of this new program was "to monitor and report customer orders of controlled substances which fit the suspicious order criteria outlined in 21 CFR § 1301.74 (b)."[31]

77. In describing the program to Mr. Gitchel, Bergen Brunswig clearly outlined, and Mr. Gitchel confirmed, that the reports submitted to the DEA would have the active ingredient ***shipped***.[32]

78. The DEA, therefore, understood that Bergen Brunswig's suspicious order reports would include orders that had already been shipped.[33]

79. There is no requirement in the regulations that suspicious orders must be reported prior to shipment, and neither Mr. Gitchel, nor anyone else at DEA, told Bergen Brunswig that this program was not compliant with the regulations. Indeed, as set forth below, the DEA ultimately approved the nationwide implementation of this program.

[27] *Id.* at 89; US-DEA-00025672.
[28] *See* ABDCMDL00315783 at 88.
[29] *See id.*
[30] *See* ABDCMDL00315783 at 86.
[31] ABDCMDL00315783 at 91.
[32] *See* ABDCMDL00315783 at 89, 92; US-DEA-00025672.
[33] *See* Dep. of Thomas. Prevoznik, May 17, 2019, at 1098:6-9 ("So these would be suspicious orders that were reported to the DEA after they had already been shipped, right? A. Right."); *Id.*, at 1118:5-10 ("Q. All right. And at least to Tom Gitchel, his understanding of what was being proposed is a daily fax of suspicious orders that would include, among other information, the amount that was shipped, correct? A. Correct.").

3. Bergen Brunswig's Use Of A Multiplier Of Three To Determine Thresholds Was Reasonably Based On Appendix E-3 of the Chemical Handler's Manual.

80. To determine what orders to place on its new suspicious order reports, Bergen Brunswig applied a multiplier of three to a customer's prior four month average order history.[34]

81. Determination of what multiplier would be used was a function left to the discretion of the distributor.

82. In determining what multiplier to use, Bergen Brunswig relied on past multipliers it had used and, in part, on the Chemical Handler's Manual, a manual that defined when an order for a listed chemical was to be considered suspicious.[35] The Chemical Handler's Manual was developed as part of the Suspicious Order Task Force forced as a result of the Methamphetamine Control Act.[36] Mr. Zimmerman participated on the Suspicious Order Task Force.[37]

83. The Chemical Handler's Manual set forth a "voluntary formula for use by distributors" of listed chemicals.[38] That formula "calculates the quantity which, if exceeded in one month, constitutes an order which may be considered excessive or suspicious and therefore require reporting to DEA."[39] The appendix instructed distributors handling chemicals to use a multiplier of three for C-II and C-III controlled substances.[40]

84. In its July 23, 1998 letter approving Bergen Brunswig's new program, DEA specifically noted that it delayed issuing final approval for Bergen Brunswig to implement its new program nationwide because it was more appropriate to wait for the work of the Suspicious Order Task Force to conclude.[41]

85. The multiplier of three that Bergen Brunswig used was included in ABDC's testing and approved by DEA in 1998, as it had been historically in ABDC's pre-1998 program.[42]

86. In my opinion, Bergen Brunswig's selection of a multiplier of three, in addition to being approved by the DEA as discussed more fully below, was sound and reasonable.

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[34] Dep. of Chris Zimmerman, August 3, 2018, at 123:16-124:7; 125:21-126:4.
[35] *See* Chris Zimmerman Dep. Exhibit 4 (Aug. 3, 2018).
[36] King, John H., U.S. Department of Justice, Drug Enforcement Administration, Diversion Control Division, *Notice of Establishment of Task Force on Suspicious Orders,* https://www.deadiversion.usdoj.gov/fed_regs/notices/other/tf_established.htm. (Last Visited May 28, 2019).
[37] Dep. of Chris Zimmerman, August 3, 2018, at 126:6-129:19.
[38] Chris Zimmerman Dep. Exhibit 4 (Aug. 3, 2018), at p. 43; Chris Zimmerman Dep., August 3, 2018, at 128:16-134:11.
[39] Chris Zimmerman Dep. Exhibit 4 (Aug. 3, 2018), at p. 43.
[40] *Id.*
[41] ABDCMDL00315783; US-DEA-00025671.
[42] Dep. of Chris Zimmerman, August 3, 2018, at 126:6-129:19.

4. The DEA Approved Bergen Brunswig's Program For Nationwide Implementation.

87. On July 23, 1998, Patricia Good, the DEA's then-Chief of the Liaison and Policy Section, "grant[ed] approval of [Bergen Brunswig's] request to implement on a nationwide basis your newly developed system to identify and report suspicious orders for controlled substances and regulated chemicals, as required by Federal regulation."[43]

88. The DEA admitted that Ms. Good approved Bergen Brunswig's suspicious order monitoring system that reported suspicious orders to the DEA after the orders had already been shipped.[44]

89. In my opinion, this approval reinforces and formally establishes that Bergen Brunswig's suspicious order monitoring system, implemented nationwide in 1998, maintained effective controls against diversion and effectively detected and reported suspicious orders.

90. Even without this formal approval from the DEA, based on my background, training, experience, and review of the information produced in this litigation, as well as interviews I conducted with ABDC personnel, it is my opinion that Bergen Brunswig's 1998 system to detect and report suspicious orders maintained effective controls against diversion and was an effective system to detect and report suspicious orders pursuant to 21 CFR § 1301.74. The 1998 diversion control program was reasonable as designed and executed by ABDC.

C. Between 1998 And 2007, ABDC Maintained A Cooperative Relationship With The DEA.

91. In 2001, Bergen Brunswig and AmeriSource Health merged forming AmerisourceBergen Drug Corporation ("ABDC").[45] The newly formed ABDC adopted Bergen Brunswig's 1998 diversion control program. This program was maintained from 1998 to 2007.

92. From 1998 to 2007, ABDC continued to work with various field offices and tailored the information to the specific requests of those field offices.[46]

93. During this time, ABDC maintained a cooperative relationship with the DEA. For example, ABDC assisted with DEA investigations.[47] In helping the DEA with

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[43] ABDCMDL00315783; *see also* US-DEA-00025671 ("subject: approve suspicious order monitoring system").
[44] *See* Dep. of Thomas Prevoznik, May 17, 2019, at 1139:10-16 ("Q: Okay. Mr. Prevoznik, the DEA approved for implementation nationwide a suspicious order monitoring system that reported orders to the DEA on a daily basis after the report – after the orders had already been shipped, correct? A. Yes.").
[45] AmerisourceBergen, *Our History*, https://www.amerisourcebergen.com/abcnew/about-our-history. (Last Visited May 28, 2019).
[46] *See, e.g.*, ABDCMDL00401601 (Dallas distribution center changed threshold limit from 3 times the normal monthly ordering pattern of a customer to 6 times based on telephone conversation with DEA's Dallas field office); *see, e.g.*, ABDCMDL00315974 (Orlando distribution center began running queries to submit additional reporting to DEA at the request of a DEA field office); *see also* ABDCMDL00315968; ABDCMDL00316041 (examples of daily suspicious order reports sent to DEA field offices by various ABDC distribution centers).
[47] ABDCMDL00398309 at 10; ABDCMDL00398338 at 43-45.

investigations, ABDC was asked by the DEA to continue to ship to customers the DEA was investigating.[48]

94. In June 2003, the DEA awarded ABDC with a Certificate of Appreciation for ABDC's involvement in an investigation of a pharmacy.

95. ABDC also helped train DEA's diversion investigators.[49] In October 2004, the DEA gave ABDC an award in recognition of ABDC's contribution to drug enforcement and to DEA's training program.[50] The DEA noted that ABDC was deserving of this recognition.[51]

96. Additionally, on August 10, 2005, ABDC met with the DEA at a distributor initiative meeting to help investigate internet pharmacies.[52] The purpose of this meeting "was to address the illegal domestic Internet pharmacy problem and their sources of supply."[53] At this meeting, the DEA gave ABDC a questionnaire that the DEA indicated should be used for due diligence of internet pharmacies.[54] Subsequently, ABDC worked with the DEA to address the rising problem of illegal internet pharmacy sales.[55] For example, ABDC began using the new DEA-generated form, which ABDC called a "Form 590."[56]

97. Based on my background, training, education, experience, and my review of the information produced in this litigation, among other things, it is my opinion that ABDC's cooperative relationship with DEA assisted ABDC in maintaining effective controls against diversion.

D. Following A Shift At DEA And An Enforcement Action At ABDC's Orlando Distribution Center, ABDC Implemented Changes To Its Diversion Control Program.

1. Due To A Sea Change At The DEA, DEA's Guidance To Registrants Changed, and ABDC Was the Subject of an Enforcement Action.

98. In 2006, Joseph Rannazzisi, who had worked exclusively on the enforcement side of the DEA, took over as the Deputy Assistant of the Office of Diversion Control.[57] Before Mr. Rannazzisi, Bill Walker was the Deputy Assistant of the Office of Diversion Control.[58] When Mr. Rannazzisi took over Mr. Walker's position, there was a shift in the DEA's positions, guidance, and willingness to work with distributors.

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[48] ABDCMDL00398234 at 35; ABDCMDL00301214 at 18.
[49] *See* ABDCMDL00315829; ABDCMDL00315862; ABDCMDL00315795; ABDCMDL00315827.
[50] ABDCMDL00398338 at 43.
[51] Dep. of Thomas Prevoznik, May 17, 2019, at 1146:7-16 ("Do you recall DEA awarded AmerisourceBergen a certificate of appreciation in 2004? . . . The Witness: Yes. Q: Okay. And they were deserving of that recognition? . . . The Witness: Yes.").
[52] *See* US-DEA-00000147.
[53] *Id.*
[54] ABDCMDL00315887 at 966-67.
[55] *See, e.g.*, ABDCMDL00398249.
[56] ABDCMDL00398249 at 53.
[57] *See* Dep. of Joseph Rannazzisi, May 15, 2019, at 391:2-18.
[58] *See id.*

99. Whereas under Mr. Walker, the DEA took a collaborative, symbiotic approach to the pharmaceutical distributors, after Mr. Rannazzisi took over, the DEA began importing enforcement-side tactics and approaches into the diversion side of DEA.

100. On September 27, 2006, Joseph Rannazzisi sent a "Dear Registrant" letter to ABDC, as well as other distributors.[59] In this letter, Mr. Rannazzisi stated that "DEA recognizes that the overwhelming majority of registered distributors act lawfully and take appropriate measures to prevent diversion."[60] Mr. Rannazzisi emphasized that distributors must "consider the totality of circumstances" when evaluating whether an order is suspicious.[61]

101. Then, on April 19, 2007, DEA issued an Order to Show Cause and Immediate Suspension of Registration for ABDC's Orlando, FL distribution center ("ISO").[62] The ISO alleged that ABDC "failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels."[63]

102. On April 27, 2007, three days after serving the original ISO, DEA issued an Order of Special Dispensation and Agreement that permitted the Orlando distribution center "to distribute controlled substances to hospitals, clinics, Department of Defense facilities; to a pharmacy that is located within and exclusively serves a hospital, clinic, or Department of Defense facility; and to the facilities of PMSI, Pharmerica, and Kindred HealthCare (and their respective subsidiaries)."[64] ABDC was also permitted to distribute controlled substances to individual practitioners who were "dispensing physicians through May 4, 2007."[65]

103. ABDC and DEA had regular meetings between April and June 2007 at DEA Headquarters.

104. Also during that same time period, personnel from ABDC's Corporate Security and Regulatory Affairs ("CSRA"), particularly Steve Mays and Jim Jackson, worked closely with Michael Mapes (DEA), Scott Davis (DEA), and Kyle Wright (DEA) on developing a new system to detect and report suspicious orders.[66]

105. In general, during this time period, DEA worked hand-in-hand with ABDC in developing its enhanced diversion control program.

106. Mr. Mapes, Mr. Wright, and Mr. Davis spent more than a week on-site at ABDC's Chesterbrook, PA headquarters, working alongside ABDC on the new order monitoring program, and reviewing ABDC's due diligence files.

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[59] ABDCMDL00269683 at 94
[60] *Id.*
[61] *Id.*
[62] ABDCMDL00269383.
[63] *Id.* ABDC had already cut off supplying controlled substances to some of the pharmacies named in the ISO. *See* ABDCMDL00398309 at 11.
[64] ABDCMDL00398334.
[65] *Id.* at 35.
[66] Dep of Stephen Mays, October 24, 2018, at 246:6-247:15, 254:18-258:9.

107. In no instance did DEA indicate to ABDC that any of these ABDC customer due diligence files were deficient. Nor did DEA indicate that ABDC's decisions to continue servicing those customers were flawed or questionable.

108. DEA and ABDC entered into a Settlement and Release Agreement on June 22, 2007.[67] Given DEA's extensive involvement, ABDC understood that DEA's entry into that Settlement and Release Agreement, as well as the return of ABDC's Orlando distribution center license, signaled effective approval of ABDC's enhanced order monitoring program and ABDC's due diligence procedures.

109. DEA's Settlement and Release Agreement with ABDC did not include any fine or financial penalty. The Agreement states that it is not "an admission of liability by AmerisourceBergen" and "AmerisourceBergen expressly denies the DEA's allegations."[68]

110. As a result of the ISO and Settlement and Release Agreement, ABDC:

- Created a diversion control team within the CSRA department for purposes of conducting due diligence inquiries and reviewing orders of interest;[69]
- Launched the Form 590 nationwide to be completed by all new customers as well as by existing customers whose orders had been flagged by ABDC's order monitoring program;[70]
- Agreed to report all controlled substances transactions to DEA headquarters on a daily basis;[71]
- Created and implemented an enhanced order monitoring program which was designed to hold orders that were flagged by the computer system for further evaluation, rather than shipping them as had been done under the prior diversion control programs;[72]
- Agreed to implement all of these changes on a nationwide basis.[73]

111. DEA agreed to review the operation of ABDC's new order monitoring program ("OMP" or "legacy OMP") and due diligence program, and to meet with ABDC yearly.[74]

112. The DEA also agreed to "conduct reviews of the functionality of AmerisourceBergen's diversion compliance program ("Compliance Reviews") at up to five distribution centers of AmerisourceBergen, consisting of the distribution centers located in

[67] ABDCMDL00279854-61.
[68] *Id.* at 55.
[69] ABDCMDL00004578 at 4580; Dep. of Stephen Mays, October 24, 2018, at 207:17-209:13; Dep. of Kyle Wright, February 28, 2018 at 135:24-137:7, 140:1220.
[70] Dep of Chris Zimmerman, August 3, 2018, at 201:11-203:17; Dep. of Stephen Mays, October 24, 2018, at 250:23-251:20.
[71] ABDCMDL00279854 at 55.
[72] *Id.*
[73] Dep. of Chris Zimmerman, August 3, 2018, at 27:13-28:2; ABDCMDL00279854.
[74] ABDCMDL00279854 at 58.

Orlando, Florida; Sugar Land, Texas; Williamston, Michigan; and two other distribution centers selected by DEA."[75]

113. ABDC presented DEA with and made aware of all of the changes ABDC made in connection with the ISO and Settlement and Release Agreement.

114. The DEA tested ABDC's new diversion control program which is described below.

2. As a Result of the ISO and Settlement and Release Agreement, ABDC Implemented An Enhanced Diversion Control Program.

115. Based on my background, training, education, experience, and my review of the information produced in this litigation, among other things, it is my opinion that ABDC's 2007-2015 diversion control program maintained effective controls against diversion and was an effective system to detect and report suspicious orders pursuant to 21 CFR § 1301.74. The diversion control program was reasonable as designed and executed by ABDC. The below section summarizes the 2007 Diversion Control Program.

a) ABDC Developed A Centralized Diversion Control Team.

116. As part of the enhancements presented to DEA in connection with the 2007 Orlando ISO, ABDC launched a dedicated diversion control team at ABDC headquarters.[76] There were several diversion investigators responsible for reviewing orders flagged by the OMP. These investigators were also responsible for reviewing new customer due diligence and reviewing due diligence for existing customers if an existing customer had an order that was flagged by the OMP.[77]

117. Each person involved in the OMP was required to attend ABDC's "OMP Training" initially and yearly trainings thereafter.[78]

118. This diversion control team was in addition to the existing security team responsible for ensuring that cages, vaults, and transportation are handled appropriately.

119. ABDC had three pillars to its 2007-2015 diversion control program: (1) new customer due diligence; (2) an order monitoring program that flagged orders of interest and were reviewed by a trained diversion control team member; and (3) ongoing customer due diligence. In addition, in 2007, ABDC also began submitting daily reports of all controlled substance transactions to the DEA.[79]

[75] ABDCMDL00279854 at 56.
[76] ABDCMDL00004578 at 80; Dep. of Stephen Mays, October 24, 2018, at 207:17-209:13; Dep. of Kyle Wright, February 28, 2019, at 135:24-137:7, 140:12-20.
[77] ABDCMDL00004578 at 80-84.
[78] ABDCMDL00004603 at 25; ABDCMDL00004603 at 38-54.
[79] ABDCMDL00004603 at 28; ABDCMDL00279854.

120. At a Pharmaceutical Industry Conference in Houston, Texas on September 11-12, 2007, DEA presented ABDC's 2007 diversion control program to the industry and held this program up to the industry as an exemplar program.[80]

121. On December 27, 2007, after Mr. Zimmerman presented at the Pharmaceutical Industry Conference alongside Mr. Mapes of the DEA, Mr. Rannazzisi issued another "Dear Registrant" letter.[81] The DEA noted that filing a monthly excessive purchase report did not meet the regulatory requirement to report suspicious orders.[82] Despite this, the DEA did not change the regulation. Mr. Rannazzisi also admitted in this letter that the DEA had approved diversion control programs in the past.[83]

122. This letter was new guidance from the DEA that was inconsistent with the system to identify and report suspicious orders that Bergen Brunswig developed, and ABDC later adopted, with the DEA between 1996 and 1998.

b) ABDC Implemented More Rigorous New Customer Due Diligence.

123. To onboard new customers, ABDC created a Form 590 based on DEA guidance to be completed by the owner of the pharmacy during an on-site visit, where an ABDC employee took pictures of the pharmacy, and a CSRA team member reviewed and verified the responses on the Form 590.[84]

124. Pursuant to ABDC's agreement with DEA in 2007, it launched the Form 590 nationwide for all new retail pharmacy customers, as well as customers which had orders that were flagged by the OMP. Retail chain pharmacies and hospitals were exempted by DEA from completing the Form 590.[85] The Form 590 questionnaire gave ABDC significant information, including the:

- amount of controlled substances ordered;
- anticipated ratio of controlled substances purchased vs. total purchases;
- key prescribing doctors in the area utilizing the pharmacy; and
- payment practices of the pharmacy's customers.[86]

[80] ABDCMDL00046628; United States Drug Enforcement Administration – Diversion Control Division, *Pharmaceutical Industry Conference* (Sept. 11, 2007) https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/13th_pharm/index.html.
[81] ABDCMDL00269683 at 85.
[82] *Id.*
[83] *Id.* ("Past communications with DEA, whether implicit or explicit, that could be construed as approval of a particular system for reporting suspicious orders, should no longer be taken to mean that DEA approves a specific system.").
[84] ABDCMDL00004603 at 4-8.
[85] Dep. of Chris Zimmerman, August 3, 2018, at 213:24-214:14; ABDCMDL00269266.
[86] ABDCMDL00004578 at 82; *see also* ABDCMDL00293362.

c) ABDC Implemented A New Order Monitoring Program That Included Human Review

125. In response to DEA's concerns about the industry's practice of shipping suspicious orders and in consultation with DEA, ABDC developed a system that would hold orders that exceeded ABDC's thresholds pending investigation.[87] ABDC would then review the order and determine whether it met DEA's definition of a suspicious order; if so, ABDC would not ship the order.[88] If it was not suspicious, then the order would ship.[89]

126. ABDC also worked to create a new OMP.[90] ABDC created peer groups, comparing like customers to like customers—*i.e.*, retail to retail, hospital to hospital.[91] ABDC also organized its controlled substances into drug families.[92] Finally, ABDC "sized" each of its customers into small, medium, and large (later adding an extra large category).[93] Ultimately, ABDC created new thresholds for each type and size of customer for each drug family, using a multiplier of three for ARCOS-reportable controlled substances.[94] Orders were run through an automated computer program to determine if they exceeded the customer's threshold for that particular drug family.[95]

127. Orders that hit on the thresholds would be considered "orders of interest," and would be subject to human review and evaluation for whether the order met the statutory definition of "suspicious." That human review process was called order review or order adjudication.[96] All of these OMP changes were made in consultation with DEA.[97] In addition to this, ABDC compliance employees were trained on the new program and those responsible for handling controlled substances were required to take annual compliance training.[98]

128. ABDC's 2007 program grouped customers by their DEA classification: hospital/clinic, retail pharmacy, practitioner, distributor.[99] Within each group, the customer was then classified according to its size.[100] The sizes included small, medium, large, and extra-large.[101] The size was determined by the total dollar value of prescription sales for both

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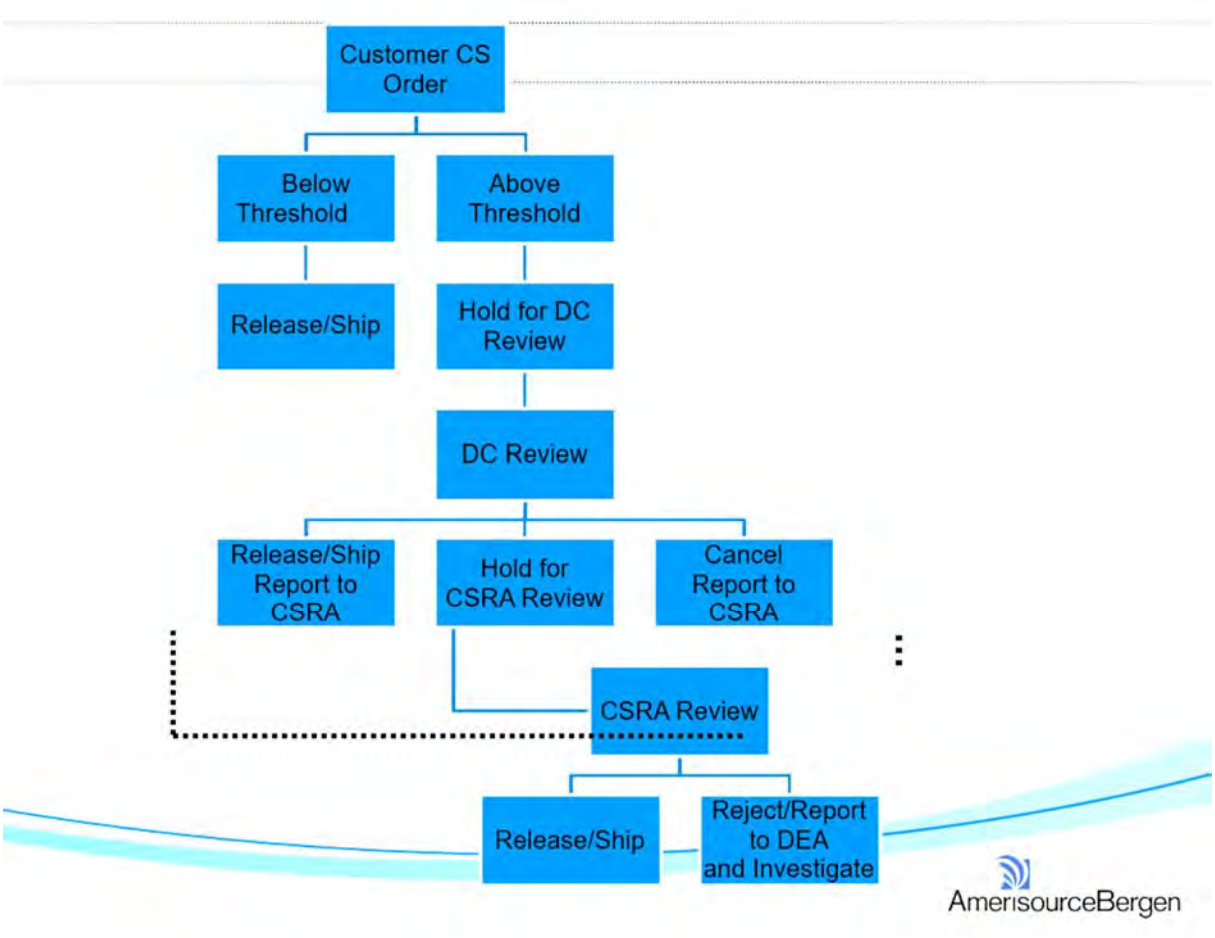
[87] Dep. of Chris Zimmerman, August 3, 2018, at 137:24-142:14.
[88] ABDCMDL00004578 at 82-83.
[89] *Id.*
[90] One concern DEA expressed was that under the 1998 DEA-approved system, a specific pharmacy's orders were compared against its own prior orders. If a customer's orders continuously rose, then the multiplier of 3x would continuously rise as well. Thus, in 2007, DEA asked that ABDC revert to a system using the 3x multiplier comparing a pharmacy's orders to similar orders by peer pharmacies.
[91] ABDCMDL00004578 at 82.
[92] ABDCMDL00004578 at 82.
[93] *Id.*
[94] *Id.*; Dep. of Chris Zimmerman, February 8, 2019, at 78:3-79:22.
[95] ABDCMDL00004578 at 82.
[96] *Id.* at 82-83, 88.
[97] *Id.* at 83; Dep. of Stephen Mays, October 24, 2018, at 246:6-247:15.
[98] ABDCMDL00004578 at 81.
[99] *See* ABDCMDL00004578 at 82.
[100] *Id.*
[101] *Id.*; *see also* ABDCMDL00004969 at 76.

controlled and non-controlled substances.[102] With DEA's knowledge, ABDC kept the multiplier of three for ARCOS controlled substances.

129. Within the categories of customers, ABDC then set a threshold for each class of drug.[103] To determine the threshold, ABDC calculated a yearly average of the order volume and then multiplied it by three.[104] If a customer ordered over this threshold over the course of 30 days, the order would be flagged as an order of interest for review.[105]

130. ABDC's OMP is illustrated in the following flowchart:[106]



131. If an order was flagged for review, it was held by ABDC until the order was investigated.[107] A trained reviewer at the Distribution Center initially reviewed the order.[108] The reviewer looked at the customer type, whether the customer had a known, legitimate, and well-

[102] ABDCMDL00004578 at 82; ABDCMDL00004969 at 76.
[103] ABDCMDL00004578 at 82.
[104] *Id.*; *see also* at ABDCMDL00004969 at 76.
[105] *Id.*; *see also at* ABDCMDL00004969 at 77.
[106] *See* ABDCMDL00264099 at p. 19.
[107] ABDCMDL00004578 at 82.
[108] *Id.*

established need for high volumes of controlled substances, and the typical ordering patterns for that customer.[109] The reviewer had three options: (1) release the order and ship it; (2) cancel the order; or (3) escalate the order for CSRA review.[110] "Generally, the OMP reviewers released Orders of Interest for hospitals and the Department of Defense."[111] A reviewer would cancel an order, but not identify it as suspicious, if, "for example, the order quantity was obviously not correct based on prior purchases or the customer reported the order as mistakenly submitted."[112] Orders that required further review—for example, a retail pharmacy exceeding its threshold—were sent to CSRA to make a final determination.[113]

132. Once an order was sent to the CSRA team for review, a CSRA representative for the particular customer's region analyzed if the order was suspicious.[114] The CSRA representative considered the totality of the circumstances surrounding the order. This totality of the circumstances review involved many factors, including: [redacted] The CSRA team member would then either: (1) determine that the order was suspicious and report it to the DEA; (2) determine that the order was not suspicious, but reject the order; or (3) release the order for shipment to the customer.[116]

133. From 2007 through present day, despite pre-2007 practice within the industry and DEA's prior explicit written approval of ABDC's after-the-fact suspicious order reporting,[117] ABDC does not ship orders it reports as suspicious to the DEA.[118]

134. In investigating customers, CSRA team members were also able to take further corrective action, including reduction of thresholds, withdrawal of the ability to purchase particular controlled substances from ABDC, or withdrawal of the ability to purchase all controlled substances from ABDC.[119]

135. In taking further corrective actions, the CSRA team made decisions on a case-by-case basis, and considered a number of factors, including:

[redacted]

[109] *Id.*
[110] *Id.*
[111] *Id.* at 83.
[112] *Id.*
[113] *Id.*
[114] *Id.*
[115] *Id.*
[116] *Id.*
[117] Dep. Chris Zimmerman, February 8, 2019, at 40:6-43:10.
[118] *See* ABDCMDL00004578 at 83; *see also* ABDCMDL00004603 at 11-12.
[119] ABDCMDL00004578 at 83.

 [120]

136. ABDC's 2007 program was ever-evolving and changed as new information became available.[121] For example,

 [122]

137. In addition, the CSRA team met monthly to discuss trends in ordering habits after analyzing purchase data to identify orders and customers that "diverged from customary purchasing."[123] They also identified and evaluated top purchasers in certain controlled substance families on an individual pharmacy basis.[124]

138. The new procedure of holding orders of interest for review caused some customer frustration, but ABDC was firmly committed to implementing and maintaining the new policies and procedures.[125] Customers would report to ABDC that other distributors were not holding or stopping orders.

139. Based on the documents I reviewed and my experience and training at the DEA, ABDC's 2007 order review went well-beyond ABDC's statutory and regulatory requirements. The program utilized many investigative techniques and struck an important balance of identifying suspicious orders while ensuring legitimate orders were shipped.

d) ABDC Implemented More Rigorous Ongoing Due Diligence.

140. In addition to enhancing its new customer due diligence and order monitoring, ABDC implemented and conducted additional ongoing due diligence of its existing customers from 2007 forward. This included, but was not limited to, site visits and pharmacy audits, audits of the OMP and distribution centers, and targeted analytics to identify customers requiring greater scrutiny.

141. First, in connection with the DEA Orlando ISO, ABDC implemented a "Do Not Ship List" in 2007. ABDC maintains a running list of customers to which ABDC will no longer ship controlled substances, or customers that ABDC declined to onboard after new customer due diligence investigations. Customers end up on the "Do Not Ship List" as a result of information

[120] ABDCMDL00004603.
[121] ABDCMDL00004578 at 83.
[122] *Id.*
[123] *Id.* at 84.
[124] *Id.*; *see also* ABDCMDL00004603 at 66-68.
[125] Dep. of Stephen Mays, October 24, 2018, at 306:22-309:4

learned by ABDC, either through its own investigations or through other sources.[126] Since 2007, ABDC has added almost 800 customers to its "Do Not Ship List" nationwide.[127]

142. Second, ABDC utilized a Form 590 with existing customers whose orders were flagged by the OMP. To complete a Form 590, an ABDC sales representative would physically go to the store location and work with the owner to complete the form.[128] Since 2007, the Form 590 has undergone frequent enhancements to take into account trends and emerging issues.[129]

143. In addition, CSRA performed targeted visits of certain retail pharmacy customers that were generally identified through the review of orders of interest or other on-going monitoring.[130]

144. ABDC took a proactive approach to constantly reviewing, adjusting, and enhancing its diversion control program through audits of its customers, OMP, and distribution centers.

145. ABDC retained Michael Mapes as an independent investigator for ABDC's pharmacy customers upon his retirement from the DEA in January 2008. From 2008 through 2013, Mr. Mapes conducted audits at ABDC customer sites.[131] During these audits, Mr. Mapes reviewed the pharmacy's compliance with controlled substance regulations.[132] When circumstances warranted, ABDC diversion team members, including Liz Garcia and Joe Tomkiewicz, would also conduct on-site audits of pharmacy customers.[133]

146. Mr. Mapes also conducted audits of ABDC's OMP.[134] During these audits, Mr. Mapes reviewed new customer due diligence files, thresholds for each drug family and customer size, ABDC's Do Not Ship List, several individual customer and drug reports, CSRA 590 forms, an audit checklist, and completed CSRA files for new customers and customers who had an increase in thresholds over the last year.[135] Although Mr. Mapes identified areas for enhancement, during a 2013 audit, Mr. Mapes noted that ABDC's "OMP is well managed and appears to be very effective at mitigating the risk associated with the distribution of controlled substances."[136]

147. In addition to Mr. Mapes' audits, ABDC's CSRA team conducted internal audits of its distribution centers to ensure the distribution centers complied with federal and state

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[126] *See, e.g.*, ABDCMDL00360259; ABDCMDL00363215; ABDCMDL00336962; ABDCMDL00337006.
[127] ABDCMDL00300218.
[128] ABDCMDL00313757; Dep. of Chris Zimmerman, August 3, 2018, 200:3-21.
[129] *See* ABDCMDL00360282; ABDCMDL00169950; ABDCMDL00364348; ABDCMDL00282315; ABDCMDL00301767; ABDCMDL00302282.
[130] ABDMCLD00004578 at 84.
[131] *See, e.g.*, ABDCMDL00003541.
[132] *See id.*
[133] ABDCMDL00163569; ABDCMDL00296193; ABDCMDL00280718-19.
[134] *See, e.g.*, ABDCMDL00398877; ABDCMDL00398882; ABDCMDL00398896.
[135] *See, e.g.*, ABDCMDL00398877.
[136] ABDCMDL00398896.

requirements.[137] During these audits, the CSRA team member reviewed policies and procedures, security measures, and customer files.[138]

148. In approximately late 2014, ABDC began to use Pharmacy Compliance Group ("PCG"), a compliance consulting company owned by Matthew Murphy, a former DEA diversion official with DEA, for certain pharmacy audits and investigations.[139] PCG consultants would visit the pharmacy site, take photos of the premises, interview pharmacy employees, including the Pharmacist in Charge, complete an on-site questionnaire, assess the pharmacy's controlled substances dispensing patterns, and review the pharmacy's recordkeeping and policies and procedures.[140] Following the visit, PCG would prepare a written report for ABDC, including, where appropriate, observations and recommendations related to the pharmacy's compliance with the relevant regulations.[141]

E. Beginning in 2014, ABDC Further Enhanced Its Diversion Control Program With Key Hires And Advanced Analytics.

149. ABDC has continued to enhance and improve its due diligence efforts, consistent with a compliance program that seeks to evolve and improve.

150. In 2014, Marcelino Guerreiro, who had been an Investigator on the Diversion Control Team, became an analyst. He took over this role from Joe Tomkiewicz.

151. Mr. Guerreiro began using a program called BOBJ to create visual reports of information that had previously been displayed to the team members only in spreadsheet form. These BOBJ reports were the precursor of what later became the FTI Tableau Customer Tear Sheets, discussed in more detail below. BOBJ allowed Mr. Guerreiro to review a pharmacy's metrics and important data points visually, with multiple metrics in a single BOBJ report (rather than disparate reports).[142] BOBJ reports would include [redacted][143]

152. Since the 2007 ISO, the DEA has conducted more than 100 audits of ABDC's distribution centers.[144] None of these audits ever resulted in a fine, immediate suspicion order, or an order to show cause.

153. In 2014, as part of its ongoing commitment to diversion control, ABDC undertook a self-critical review of its existing diversion control program.

154. Based on the self-critical review, ABDC acted to further enhance its diversion control program by hiring additional personnel with specialized experience and subject-matter

[137] *See, e.g.*, ABDCMDL00409997; ABDCMDL00402641.
[138] *Id.*
[139] ABDCMDL00252345.
[140] *See, e.g.*, ABDCMDL00000608.
[141] *See, e.g.*, *id.*
[142] *See, e.g.*, ABDCMDL00006105; ABDCMDL00247484; ABDCMDL00298447.
[143] *Id.*
[144] ABDCMDL00253869.

expertise and retaining a respected consulting firm to better utilize its data as part of its order monitoring program, human review of orders of interest, and ongoing customer due diligence.

155. Based on my background, training, education, experience, and my review of the information produced in this litigation, among other things, it is my opinion that ABDC's 2014-present day diversion control program maintained effective controls against diversion and is an effective system to detect and report suspicious orders pursuant to 21 CFR § 1301.74. The diversion control program was reasonable as designed and executed by ABDC. The below section summarizes the 2014 forward Diversion Control Program.

1. Key Hires: David May, Sharon Hartman, and FTI Consulting

156. In 2014, ABDC hired David May, a 30-year veteran of the DEA. During his time at the DEA, Mr. May held positions as Special Agent, Resident Agent in Charge, Assistant Country Attache, Staff Coordinator/Section Chief, Regional Enforcement Team Supervisor, State and Local Task Force Supervisor, and Assistant Regional director.[145] In his last role prior to leaving the DEA, Mr. May served as the Assistant Special Agent in Charge of the Atlanta Field Office. In that role, Mr. May oversaw a Tactical Diversion Squad that was responsible for investigating DEA registrants.

157. At ABDC, Mr. May has oversight of the day-to-day management of the Diversion Control Team. He also has primary responsibility for and oversight of all interactions with the DEA and state regulatory bodies as related to diversion control and suspicious order monitoring.[146]

158. Around the same time in 2014, ABDC hired Sharon Hartman to augment the diversion control team. Ms. Hartman was hired into a newly-created role as Director of Pharmacy Compliance.[147]

159. Ms. Hartman has been a licensed pharmacist (licensed by the states of Illinois and Indiana) for 35 years. Over that time, Ms. Hartman has had many different roles, including working as a retail pharmacist, working as a Medical Director, and working in Pharmacy Compliance for over 15 years.[148]

160. Ms. Hartman's responsibilities include oversight of the ongoing due diligence as to pharmacies or other customers that exhibit red flags for potential diversion. Ms. Hartman oversees pharmacy site visits and audits, reviews or oversees reviews of pharmacy dispensing data when appropriate, and provides insight and guidance to more junior members of the diversion control team on all matters related to pharmacy and pharmacological issues.[149]

161. In addition to Mr. May and Ms. Hartman, ABDC also hired a respected consulting firm, FTI Consulting, to evaluate its diversion control program.[150] ABDC sought to identify a

[145] ABDC's Objections & Responses to Plaintiffs' First Set of Interrogatories, No. 17.
[146] ABDCMDL00004969 at 73.
[147] ABDCMDL00004578 at 95.
[148] Dep. of Sharon Hartman, November 29, 2018, at 26:8-106:18 & Ex. 1.
[149] *Id.* at 46:15-24, 48:23-49:2, 53:7-10, 54:21-55:3.
[150] ABDCMDL00004578 at 86.

comprehensive, user-friendly way to best utilize the data it collected from customers both for reviewing and adjudicating orders and for conducting due diligence.[151]

2. Revised Order Monitoring Program ("ROMP")

162. From approximately February 2014 through August 2015, ABDC and FTI developed, tested, and refined enhancements to ABDC's OMP.[152]

163. The stated objectives were to better define and understand customers; expand ABDC's use of data to drive decisions and processes; take a more targeted approach to identifying orders for review; and adopt a more adaptable, flexible system and have less subjective evaluation.[153]

164. The order review and adjudication process remained fundamentally the same—orders were electronically monitored by a computer program. Every order flagged for review was reviewed by a member of ABDC's diversion control team, and either released or rejected. Suspicious orders were reported to the DEA .[154]

165. [redacted][55] The ROMP had the same approximate number of drug families as the legacy OMP.[156] But unlike the legacy OMP that had four peer groups (small, medium, large, and extra large), [redacted] as opposed to the dollar volume used by the 2007 OMP.[158]

166. Parameters in the ROMP are dynamic and refreshed annually, based on actual consumption data from the most recent 12 months.[159] Parameters under the ROMP were risk-based, and calculated using interquartile ranges and a risk-adjusted multiplier depending on the product family at issue and potential for abuse.[160]

167. Instead of the one threshold system used in the legacy OMP from 2007 to 2015, the ROMP considered [redacted][61]

168. [redacted]

[151] *Id.*
[152] ABDCMDL00004578 at 86.
[153] ABDCMDL00158886 at p. 8.
[154] *Id.* at 10.
[155] *Id.* at 11.
[156] *Id.*
[157] *Id.*
[158] *Id.*
[159] *Id.*
[160] *Id.* at 12.
[161] *Id.* at 10.

[redacted]

169. [redacted]

170. ABDC's Diversion Control Team also reviews customer ordering patterns outside of the flagged order process, so even customers whose orders were not flagged for order review could be scrutinized by ABDC and could be subject to ABDC's ongoing customer due diligence process.

3. Human Review of Orders of Interest

171. ABDC's Diversion Control Team reviews orders of interest to determine—based on the totality of the circumstances—whether to report the order as suspicious.[167] This is sometimes referred to as the adjudication process.

172. The orders flagged by ABDC's system had previously been housed in a system called "STAR," but around this time, ABDC began housing flagged orders in a system called "SAP." The use of SAP was a significant change for ABDC, as it gave reviewers an improved ability to view, analyze, and utilize data in an efficient and user-friendly manner.

173. The adjudication process for evaluating orders of interest is intensive and comprehensive. It begins when a reviewer reviews SAP information, including customer and order information.[168] The screen also shows the reviewer why the order was flagged—[redacted] For example, an SAP screen can show

[redacted]

[162] ABDCMDL00004578 at 91-92; ABDCMDL00144876.
[163] ABDCMDL00004578 at 92.
[164] *Id* at 91.
[165] *Id.*
[166] *Id.*
[167] *See* ABDCMDL00144876.
[168] *See* ABDCMDL00144876; ABDCMDL00393868.

[redacted]

174. [redacted]

175. A reviewer generally also reviews the Customer Tear Sheet, which is a dashboard with relevant information about the customer [redacted] displayed in a dynamic and comprehensive way.[170] Depending on the circumstances, an order reviewer can also consult other analytics used within the Diversion Control Team, including, for example, [redacted][173]

176. The type of information on the Customer Tear Sheets is updated and changed by ABDC and FTI on an ongoing basis depending on identified needs and trends.[174]

177. Once their totality of the circumstances analysis is concluded, Diversion Control Team members adjudicate orders of interest in SAP. A reviewer must select a reason for releasing or reporting the order from a drop-down box.[175]

178. A reviewer can also insert comments into a free form text comment box at the conclusion of the adjudication process.[176]

179. Generally, ABDC endeavors to adjudicate orders of interest within 24 hours of the order being held. This is not a hard and fast rule, however, and orders of interest may be adjudicated more quickly or more slowly, depending on the circumstances.

180. ABDC's Diversion Control Team also holds a weekly call to review orders from the past week that were reported as suspicious. This type of communication is a positive method for ensuring good communication and consistency, and ensuring that team members are up to date on recent developments.

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[169] *See* ABDCMDL00393868 at 75.
[170] *See, e.g.*, ABDCMDL00364396; ABDCMDL00364398; ABDCMDL00360400; ABDCMDL00360401.
[171] ABDCMDL00360403.
[172] ABDCMDL00254485-86.
[173] *See, e.g.*, ABDCMDL00398848; ABDCMDL00398850; ABDCMDL00398855.
[174] ABDCMDL00364396; ABDCMDL00364398; ABDCMDL00360400; ABDCMDL00360401; ABDCMDL00250005.
[175] *See* ABDCMDL00144876.
[176] *See* ABDCMDL00144876.

4. Data Used For Ongoing Customer Due Diligence And Order Adjudication

181. Starting around 2014, ABDC's Diversion Control team continued to refine and supplement their ongoing customer Due Diligence procedures. The new FTI "tableau" files or "dashboards" were used both in order review and ongoing customer due diligence.

182. Using a program called "Tableau," FTI and ABDC worked to design, test, and implement comprehensive and visually compelling dashboards, also called customer tear sheets. These dashboards present customer specific data, including [redacted]

183. Each dashboard is supported by voluminous amounts of information but present that information in a comprehensible and visually stimulating way.[177] The presentation of this data in this manner allows diversion investigators to make better decisions in both order adjudication and ongoing customer due diligence efforts.

184. In addition to the tear sheets, ABDC and FTI created higher level dashboards created on a monthly basis which looked for trends and developments across the entire customer base. For example, a "heat map" showed the various counties across the United States.[178] This map showed which counties had greater issues with overdoses and addiction.[179]

185. These powerful analytical dashboards sit on the desk of every member of ABDC's Diversion Control Team and provide valuable insight into a customer. While ABDC effectively utilized spreadsheets and other analytical tools prior to FTI's dashboards, the transition to FTI's dashboards significantly enhanced ABDC's Diversion Control Team members' ability to quickly yet thoroughly evaluate deep data.

186. ABDC also implemented a termination process. Customers that ABDC determines it no longer intends to service with controlled substances are provided with a letter and an explanation. If desired, customers can challenge the decision and submit information supporting their desire to continue to be serviced. ABDC's Senior Director of Diversion Control then evaluates and makes a determination. Customers who are terminated from receiving controlled substances are placed on the Do Not Ship List.[180]

187. Since 2018, ABDC has also been advising the DEA and relevant state Board of Pharmacy when it terminates a customer's ability to order controlled substances.

[177] ABDC Production Volumes 156, 158, 159.
[178] *Id.*
[179] *Id.*
[180] ABDCMDL00004033 at 92-93.

F. ABDC's ROMP Further Utilizes Tools, Including Annual Refreshes, Form 590 Validation Project, And A Do Not Ship List, To Enhance Its Diversion Control Program.

1. ABDC Continues To Review And Adjust The ROMP Through Annual Refreshes.

188. Because customers and circumstances are constantly evolving, shifting, and changing, ABDC's new program includes an annual self-evaluation process known as the "Annual Refresh."[181]

189. Every year, ABDC uses consumption data from the year prior to adjust and recalculate parameters and reassess the continued need for any then-existing overrides.[182]

190. The annual refresh has resulted in changes to the program, including using different multipliers to determin [redacted][183]

191. ABDC also reviews policies and procedures, product family groups, and risk assessments to account for regulatory changes to controlled substances.[184]

192. Having an annual review of its Diversion Control Program allows ABDC to modify its system as needed to maintain sufficient and effective controls in a changing environment.

2. ABDC Continues To Collect And Update Form 590s Through The Form 590 Validation Project.

193. In May 2016, ABDC started a new initiative called the "CSRA 590 Validation Project."[185] The goal of this project was to identify those customers who did not have a Form 590 on file and to have Form 590s completed for those customers.

194. Importantly, if a customer's due diligence file did not include a Form 590, that does not mean that ABDC was not in compliance as to that customer. DEA did not require that every customer have a Form 590 on file.[186] Moreover, it is possible that a Form 590 was previously completed for a customer but that it had not been maintained in the file or lost.[187]

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[181] ABDCMDL00004578 at 94.
[182] *Id.*; *see also* ABDCMDL00390248.
[183] ABDCMDL00004578 at 94.
[184] *Id.*
[185] ABDCMDL00152133.
[186] Dep. of Chris Zimmerman, August 3, 2018, at 213:24-214:14; ABDCMDL00269266.
[187] Dep. of Kevin Kreutzer, November 27, 2018, at 160:2-160:9; ABDCMDL00140921.

195. DEA's record-retention policies only require that registrants maintain records for two years, and DEA's regulations do not state that a registrant is required to maintain due diligence records.[188]

196. For all customers, including those identified by the CSRA Form 590 Validation Project, orders are put through the ROMP and adjudicated, and ABDC personnel utilize the vast swath of information in the dashboards, SAP, and other sources on these customers to adjudicate orders and conduct ongoing customer due diligence.

3. ABDC Utilizes A Do Not Ship List.

197. As previously discussed, ABDC maintains a "Do Not Ship" list, of pharmacies that are no longer permitted to order controlled substances (or particular kinds of controlled substances) due to concerns ABDC had about a heightened risk for potential diversion.

198. The Diversion control team has continued to add customers to the Do Not Ship list, and has added approximately 100 customers nationally between 2014 and May 2018.[189]

199. Pharmacies that are on the Do Not Ship list cannot place orders for controlled substances (or particular kinds of controlled substances) and, accordingly, any orders they may have hypothetically placed that would have been flagged as orders of interest are not in fact placed. Thus, as additional customers (and specifically, those customers suspected of potential diversion) are placed on the Do Not Ship list there is a corresponding decrease in the numbers of orders of interest flagged and, likely, a decrease in the number of suspicious orders reported to the DEA.

200. Based on my background, training, education, experience, and my review of the information produced in this litigation, among other things, it is my opinion that ABDC's 2015-present diversion control program maintained effective controls against diversion and is an effective system to detect and report suspicious orders pursuant to 21 CFR § 1301.74. The diversion control program was reasonable as designed and executed by ABDC.

VII. PLAINTIFFS' CRITICISMS OF ABDC'S SUPPOSED FAILURES TO MEET REGULATORY STANDARDS ARE UNFOUNDED AND FLAWED.

201. I have reviewed the expert reports of James Rafalski, Seth Whitelaw, and Dr. McCann.

202. For the reasons articulated above, their reports do not change my opinions, and I disagree with their conclusions as to ABDC.

[188] 21 CFR § 1301.74.
[189] ABDCMDL00336997; ABDCMDL00300218.

203. I do note that Seth Whitelaw's report states that "laws and regulations establish the bare minimum requirements that companies must abide by but good companies, especially those that understand the value of compliance, can and often do go farther."[190]

204. In discussing ABDC, Dr. Whitelaw's report asserted that "ABC, and those responsible for the controlled substances program, not only were conversant with the DEA's expectations for distributors, but they worked to configure a program that only addressed the bare minimums."[191]

205. And when asked during his deposition what "bare minimums" meant, Mr. Whitelaw confirmed that indeed ABDC had been compliant with the regulations in his view.[192]

206. In my opinion, ABDC's Diversion Control Program goes well-beyond the requirements and does not just meet the minimum standard for compliance. In my opinion, ABDC's Diversion Control Programs throughout the years have all far exceeded the statutory and regulatory requirements.

[190] Expert Report of Dr. Seth Whitelaw at 5-6 (Apr. 15, 2019).
[191] *Id.* at 128.
[192] Dep of. Dr. Seth Whitelaw, May 17, 2019, at 649:12-650:7.

Respectfully Submitted,

Robert L. Buskey

Date: 5/31/2019

APPENDIX A

BUSKEY – MATERIALS REVIEWED AND CONSIDERED

Deposition Transcripts
Transcript of Eric Cherveny Deposition, 2018.11.09, with exhibits
Transcript of Stephen Mays Deposition, 2018.10.24, with exhibits
Transcript of Chris Zimmerman Deposition, 2018.08.03, with exhibits
Transcript of David May Deposition, 2018.08.04, with exhibits
Transcript of Elizabeth Garcia Deposition, 2018.12.14, with exhibits
Transcript of Kevin Kreutzer Deposition, 2018.11.27, with exhibits
Transcript of Gabriel Weissman Deposition, 2019.01.17, with exhibits
Transcript of Rita Norton Deposition, 2019.01.09, with exhibits
Transcript of Nikki Seckinger Deposition, 2018.12.12, with exhibits
Transcript of Sharon Hartman Deposition 2018.11.29, with exhibits
Transcript of Nathan Elkins Deposition, 2018.11.14, with exhibits
Transcript of Bruce Gundy Deposition, 2018.11.07, with exhibits
Transcript of Edward Hazewski Deposition, 2018.10.25, exhibits
Transcript of Joseph Tomkiewicz Deposition, 2018.11.28, with exhibits
Transcript of Steve Mays Deposition, 2019.02.08, with exhibits
Transcript of Chris Zimmerman Deposition, 2019.02.08, with exhibits
Transcript of Demetra Ashley Deposition, 2019.03.15, with exhibits
Transcript of Kyle Wright Deposition, 2019.03.04, with exhibits
Transcript of Kyle Wright Deposition, 2019.02.28, with exhibits
Transcript of Derek Siegle Deposition, 2019.01.23, with exhibits
Transcript of Keith Martin Deposition 2019.04.03, with exhibits
Transcript of Thomas Prevoznik Deposition, 2019.4.18, with exhibits
Transcript of Thomas Prevoznik Deposition, 2019.4.17, with exhibits
Transcript of Thomas Prevoznik Deposition, 2019.05.17, with exhibits
Transcript of Marcelino Guerreiro Deposition, 2019.04.03, with exhibits
Transcript of Stacy Harper-Avilla Deposition, 2019.4.11, with exhibits
Transcript of Joseph Rannazzisi Deposition, 2019.4.26, with exhibits
Transcript of Seth Whitelaw, 2019.5.17, with exhibits

BUSKEY – MATERIALS REVIEWED AND CONSIDERED

Court Documents
Plaintiffs' Responses to the Amended and Clarified Discovery Ruling 12 Supplemental Interrogatory Issued to Plaintiffs
Plaintiffs' Response to Supplemental Interrogatory Issue in Discovery Ruling 12 to Plaintiffs
Novelty Distributors, Inc.; Revocation of Registration, 73 Fed. Reg. 52689 (Sept. 10, 2008)
Cardinal Health, Inc.'s Third Supplemental Objections and Responses to Plaintiffs' First Combined Discovery Requests
Plaintiff Cardinal Health Inc.'s Reply in Support of Motion for Preliminary Injunction, No. 1:12-cv-00185-RBW (D.D.C. Feb. 13, 2012)
Cuyahoga Second Amended Complaint
Cleveland Second Amended Complaint
Summit Second Amended Complaint
Summit Third Amended Complaint
Discovery Ruling No. 12 re: Suspicious Order Intgerrogatory
ABDC's Objections & Responses to Plaintiffs' First Set of Interrogatories

Other Documents and Materials
21 U.S.C. § 830
Drug Abuse Control Amendments – 1970, Hearings, Ninety-First Congress, Second Session, on H.R. 11701 and H.R. 13743, at 206, 269, 417-18, 476
21 C.F.R. § 1301.74
36 Fed. Reg. 7776 (1971)
36 Fed. Reg. 4928 (1971)
21 U.S.C. § 801
Quality Management Systems – Reuquirements, International Standard (5th ed. September 9, 2015), Reference No. ISO 9001:2015(E)
2001 Chemical Handler's Manual https://web.archive.org/web/20010604221806/http://www.deadiversion.usdoj.gov/pubs/manuals/chem/chem2001.pdf
2000.10 TOC Chemical Handler's Manual https://web.archive.org/web/20001207232300/http://www.deadiversion.usdoj.gov/pubs/manuals/chem/index.html
2001.11 TOC Chemical Handler's Manual https://web.archive.org/web/20020810184247/http://www.deadiversion.usdoj.gov/pubs/manuals/chem/index.html
Interview with David May (Feb. 26, 2019)
Interview with Chris Zimmerman (Feb. 26, 2019)
Interview with Steve Mays (May 30, 2019)
Interview with Marcelino Guerreiro (May 22, 2019)
AmerisourceBergen, *Our History*, https://www.amerisourcebergen.com/abcnew/about-our-history.
King, John H., U.S. Department of Justice, Drug Enforcement Administration, Diversion Control Division, *Notice of Establishment of Task Force on Suspicious Orders,* https://www.deadiversion.usdoj.gov/fed_regs/notices/other/tf_established.htm
United States Drug Enforcement Administration – Diversion Control Division, *Pharmaceutical Industry Conference* (Sept. 11, 2007) https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/13th_pharm/index.html.

BUSKEY – MATERIALS REVIEWED AND CONSIDERED

Expert Reports
2019.4.15 Expert Report of James Rafalski
2019.4.15 Expert Report of Seth Whitelaw
2019.5. 10 Supplemental Report of Seth Whitelaw
2019.4.15 Expert Report of Stephen Schondelmeyer
2019.4.15 Expert Report of Lacey Keller
2019.3.25 Expert Report of Dr. Craig McCann
2019.4.3 Supplemental Report of Dr. Craig McCann
2019.4.15 Second Suplemental Report of Dr. Craig McCann
2019.05.10 Expert Report of Dennis Wichern

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BUSKEY – MATERIALS REVIEWED AND CONSIDERED

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APPENDIX B

ROBERT L. BUSKEY

2107 Peninsula Drive, Lake Wylie, South Carolina 29710
rbuskey@thebellbuskeygroup.com
718.986.1508

2011-present: Co-Founder and Managing Director, BBG Consulting LLC: BBG Consulting is a risk management firm operating in the areas of compliance, investigations, due diligence, business integrity, safety and security. *A New York State licensed Private Investigation company.*

Manage the day to day operations of the company, business development, project manager and practice leader on the company's service offerings: pharmaceutical and banking compliance, physical security (video surveillance and access control) and due diligence.

Expert in the following areas: Title 21 Code of Federal Regulations (CFR), Controlled Substances Act (CSA), Federal Corruption and Practices Act (FCPA), Office of Foreign Assets (OFAC) regulations, Bank Standards Act (BSA).

ACCOMPLISHMENTS

- Conducted on site reviews and revision of Standard Operating Procedures for major pharmaceutical companies.
- Conducted on site reviews on behalf of Pharmaceutical Distribution companies to augment their Compliance Department's order monitoring program. Insuring they meet compliance requirements by analyzing dispensing reports, identifying red flags and excessive dispensing by Pharmacy clients. Review: record keeping, handling of controlled substances, security apparatus, and due diligence policy; identify suspicious prescribers and verify credentials.
- Managed the installation the access controls and placement of over 60 video surveillance cameras in a medical facility

ADDITIONAL ACCOMPLISHMENTS

- Supervised over 60 law enforcement personnel and included airport interdiction at area airports.
- Managed sensitive Programs: Tactical Diversion Squad, a hybrid group, conducted investigations upon pharmaceutical companies and persons involved in the diversion of scheduled controlled substances.
- Managed statewide Mobile Enforcement Team aimed at violent repeated offenders operating in locations with limited enforcement resources.
- Member of the DEA Office of Inspections Crisis Management Team (FBI certified).
- Supervised the Non Drug Evidence area; as a project manager reorganized over 50k pieces of evidence; cataloged all of the items within a database system; and conducted an inventory of all items.
- Managed the recruitment process for the State of New York. Developed marketing strategies and managed the recruitment, background investigation and actual selection process.
- Initiated and managed the collegiate Cooperative Education Internship Program, as well as, authored and established the Student Volunteer Service Program. Recruited colleges and students to participate in this program.
- DEA cover program liaison with the US State Department and Central Intelligence Agency.

- Tracked and traced assets gained through laundering money and the transport bulk currencies domestically and internationally.
- Held a Top Secret security clearance.
- See detailed employment experience for more accomplishments.

ADDITIONAL EMPLOYMENT EXPERIENCE

1986-2011: Drug Enforcement Administration (DEA), New York Field Division, Supervisory Special Agent/Criminal Investigator: Criminal Investigator, Recruitment Coordinator, Non-Drug Evidence Custodian, Supervisory Special Agent (Group Supervisor, Staff Coordinator, Inspector, and Assistant Special Agent in Charge). Held a Top Secret security clearance with access to the Sensitive Compartmented Information Program (SI, TK, HCSP, and G):

2010-2011: Assistant Special Agent in Charge, Division 30, New York Field Division: Supervised four Group Supervisors and over 60 federal, state and local law enforcement officers in various missions to disrupt and dismantle drug trafficking organizations. Achieved this goal by the use of surveillance (electronic and telephonic), undercover operations, the development of credible sources of information, and sound leadership. Managed the domestic and international operations to disrupt and dismantle money laundering and drug trafficking organizations at New York area airports. Identified assets for seizure and foiled money laundering schemes. Administered official performance evaluations and made recommendations for personnel actions to the head of office. Conducted case briefings and participated in functional committees involving case management, self inspection and promotions. Coordinated, managed and distributed classified investigated leads throughout the division. Managed the case develop using data systems that quantify the use of man hour versus case results.

2006-2010: Supervisory Special Agent, Tactical Diversion Squad, New York Field Division: Manage a new initiative investigative hybrid unit, consisting of Special Agents and Diversion Investigators whose mission is to dismantle and disrupt drug trafficking organizations facilitating, diverting and distributing scheduled pharmaceuticals, controlled substances, and List One chemicals. Supervise and formulate strategies to combat those persons, DEA Registrants, and criminal syndicates violating the law via the Internet. Tracked and traced assets gained through laundering money and the transport bulk currencies domestically and internationally. Member of the self-inspection and review team and of the Special Agent promotion review committee. Most recently, supervised investigations "Operation Raw Deal" and "Operation Click4Drugs".

2005-2006: Acting Assistant Special Agent in Charge, Division 40, New York Field Division: Supervised five Group Supervisors and 50 federal, state and local law enforcement officers in various missions to disrupt and dismantle drug trafficking organizations. Achieved this goal by the use of surveillance (electronic and telephonic), undercover operations, the development of credible sources of information, and sound leadership. Administered official performance evaluations and made recommendations for personnel actions to upper-management. Managed a new squad, consisting of Special Agents and Diversion Investigators whose mission was to dismantle and disrupt drug trafficking organizations facilitating, diverting and distributing scheduled pharmaceuticals controlled substances and List One chemicals.

2002-2005: Inspector, DEA HQs, Office of the Inspector General, Office of Inspections: Conducted On-Site Inspections of DEA components, in both HQs and Field Offices, to determine mission effectiveness, audit financial operations, and made findings and recommended corrective actions to insure compliance with Department of Justice and DEA Rules, Regulations and Policies. Member of the Shooting Incident Investigative Response Team; investigated shooting incidents involving Special Agents

and Task Force Officers. A member of the Inspections Crisis Management team; developed the Inspections Crisis Management plan. Member of the Inspections Automation Committee; creating a paperless environment and electronic filing of former On-Site Inspections reports and working documents; and reviewed desk audit requests for promotions to the GS-13 level.

2001-2002: Staff Coordinator, DEA HQs, Office of Operations Management, Investigative Support Section (18 months): Managed the State and Local Task Force (deputization) program, Other Federal Law Enforcement (cross designation) program, Undercover Documents, Prisoner Transfer and Repatriation program, and classified programs. Reviewed and reworded applicable sections of the Agents Manual to reflect changes in the program and procedure. Navigated existing Statement of Work and revised and recommended and created a paperless recording, tracking and records retrieval database system for all agency deputized officers.

2000-2001: Resident Agent in Charge, Westchester New York: Supervised law enforcement officers (Federal, State and Local) in an enforcement mission to investigate, disrupt and dismantle violent drug trafficking organizations in six counties north of New York City. Track and traced assets gained through illegal enterprises.

1997-2001: Supervisory Special Agent: Mobile Enforcement Team and Westchester Task Force): Supervised and conducted criminal and civil investigations. The Mobile Enforcement Team's mission was to insert into trouble areas (with limited enforcement resources) in the State of New York and target violent and repeated offenders operating drug trafficking organization and disrupt and dismantle their organization. The Team consisted of Special Agents and other federal, state and local law enforcement entities under DEA funding and strategies. Created budget requests for funding appropriations and authorized expenses incurred by personnel during deployments away from home. As an insertion operation and enforcement initiative, the complete project from start to finish; including setting up the infrastructure, e.g. research, intelligence, funding, strategy, reporting and measuring the results.

1996-1997: Recruitment Coordinator: Managed the New York Field Division Recruitment program and served in the position for three Office Heads. Elevated the program from fifth ranked in the nation to number one within one year, based on the quantity, quality and diversity of applicants. Managed the recruitment process from recruitment to hire, ensuring the applicants success. Initiated and managed the collegiate Cooperative Education Internship Program, as well as, authored and established the Student Volunteer Service Program, and recruited colleges and students to participate in this program.

1995-1996: Non-Drug Evidence Supervisor: Managed and mentored Evidence Technicians in the processing of Non-Drug Evidence storage and inventory. Authored a proposal to reorganize the Non-Drug Evidence Area (NDEA) and reorganized over 50,000 pieces of non-drug evidence.

1991-1995: Recruitment Coordinator: Managed the New York Field Division Recruitment program.

1986-1991: Special Agent/Criminal Investigator: Conducted criminal and civil investigations of major criminal organizations, dismantling and disrupting them using state of the art investigative techniques. Investigative techniques were deployed to root out criminal activity, data mining private and public databases to detect money laundering, asset recovery fraud and criminal activity.

1983-1986: New York Health and Hospital Corporation, Office of the Inspector General, Confidential Investigator: Conducted administrative, civil and criminal investigations involving the fraud, waste and abuse of Health and Hospital personnel and contractors.

EDUCATION

Bachelor of Arts Degree in Economic and Psychology
State University of New York at Stony Brook, 1980

TRAINING

- Diversion Investigations
- General Investigations Techniques
- Conspiracy and Complex Investigations
- Inspection and Auditing
- FBI Crisis Management Coordinator (*FBI Certified*)
- Internet Investigations
- Internet Security
- Internet exploitation investigations
- Financial Investigation Techniques
- Anti-Money Laundering
- Personal Background Investigations
- Recruitment Techniques
- Advanced Asset Recovery and Forfeiture
- Telephone exploitation investigations
- Interview and Interrogation (Reid)
- Equal Employment Opportunity
- Ethics and Conflict of Interest
- Group Supervisor Institute
- Supervisor In-Service Program
- Advanced Special Agent Training
- Basic Agent Training
- Firearm/Special Weapons and Tactics
- Raid and Safety Planning

OTHER SKILLS

Proficiency in the use of Microsoft products: Outlook, Word, Access, Excel, PowerPoint and Publisher. Trained and experienced in the use of Private and Public data bases.

INTERESTS

- Free & Accepted Freemasons of the State of New York, Allied Lodge No.1170
- Ancient Accepted Scottish Rite, Lodge Council Chapter Consistory, Scottish Rite Bodies in the Valley of New York City
- Phi Beta Sigma Fraternity Inc. Life Member